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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,916

04/07/2006

Niels Joergen Madsen

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EXAMINER

GHALL, ISIS A D

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

03/01/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/574,916

Applicant(s)

MADSEN ET AL.

Examiner

Isis A. Ghali

Art Unit

1611

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 2-5, 14-20, 22-25 and 27-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6-13, 21, 26 and 37-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No.(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and request for RCE both filed 09/24/2010.

Claims 1-42 are pending.

Claims 2-5, 14-20, 22-25, 27-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/15/2009.

Claims 1, 6-13, 21, 26 and 37-42 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/24/2010 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 6-13, 21, 26, 37-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/48858 ('858, IDS filed 07/24/2006) in view of JP 07-070545 ('545, previously cited) and GB 1431683 ('683, previously cited).

Applicant Claims

Applicants' currently amended claim 1 is directed to a composition comprising:

- a) one or more hydrogel-forming hydrophilic homopolymers or heteropolymers and
- b) one or more amphiphilic block-copolymers comprising:
 - (i) one or more hydrophobic polymer blocks incompatible with the hydrogel-forming hydrophilic homopolymers or heteropolymers and
 - (ii) one or more hydrophilic polymer blocks, including a hydrophilic end block, compatible with the hydrogel-forming hydrophilic homopolymers or heteropolymers.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

WO '858 teaches pressure sensitive adhesive composition for application to human or animal skin comprising polyvinyl pyrrolidones polymer (PVP) or PVP copolymer, and block copolymer comprising styrene to improve the rate of absorption of water and improve integrity and wet tack of the adhesive composition on wet skin (abstract). PVP has capability to absorb water (page 7, lines 13-16), i.e. hydrogel forming polymer. The composition further comprises hydrocolloid selected from polyethylene glycol, which reads on plasticizer claimed by claim 8 (page 9, line 7).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Although WO '858 teaches the adhesive composition comprises block copolymer comprising styrene to improve the rate of absorption of water and improve integrity and wet tack of the adhesive composition on wet skin, however, the reference does not explicitly teach amphiphilic block-copolymers comprising hydrophobic polymer blocks and hydrophilic end block polymer as instantly claimed by claim 1.

JP '545 teaches adjustable pressure sensitive adhesive suitable for medicine delivery comprising copolymer having in the polymer molecule hydrophilic part such as polyethylene glycol and hydrophobic part such as styrene polymers. The pressure sensitive adhesive has adjustable pressure sensitive adhesiveness. The teaching of the reference encompasses all copolymer configuration including diblock and triblock copolymers. Both polymer do not dissolve in each other and suitable for drug delivery. (See abstract; paragraphs 007-0014).

GB '683 teaches triblock as well as diblock copolymers having low glass temperature comprising hydrophobic styrene B polymers and hydrophilic polyethylene A polymers. The block copolymers have high water absorption capacity and can be used as surfactant and emulsifier. The references teaches BA and BAB block copolymers wherein block B is the hydrophobic and block A is the hydrophilic, hence BA polymer has hydrophilic end block. The molecular weight of hydrophobic block B is between 1,000 and 500,000 and molecular weight of hydrophilic block A is between 1,000 and 500,000. (See page 1, lines 46-90; page 2, lines 54-57, 85-100, 130; page 3, lines 1-2, 76-86; page 4, lines 109-115).

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide pressure sensitive adhesive composition for application to human or animal skin comprising polymer or copolymer PVP and block copolymer comprising styrene to improve the rate of absorption of water as taught by WO '858, and replace the block copolymer comprising styrene with copolymer comprising hydrophobic block and hydrophilic block as taught by JP '545 and further use block copolymer having hydrophobic block polymer having MW between 1,000 and 500,000 and hydrophilic end block polymer having MW between 1,000 and 500,000 as taught by GB '683. One would have been motivated to do so because WO '858 desired to improve water absorption and because JP '545 teaches that copolymers having hydrophilic and hydrophilic polymers in the molecules are suitable for medicinal delivery and provides adjustable pressure sensitive adhesiveness, and because GB '683 teaches that block copolymers having hydrophobic block polymer having MW between 1,000 and 500,000 and hydrophilic end block polymer having MW between 1,000 and 500,000 have low glass temperature, have high water absorption capacity and can be used as surfactant and emulsifier. One would reasonably expect formulating pressure sensitive adhesive composition for application to human or animal skin comprising polymer or copolymer of PVP and block copolymers having hydrophobic block polymer having MW between 1,000 and 500,000 and hydrophilic end block polymer having MW between 1,000 and 500,000 wherein the adhesive has adjustable adhesiveness, high

water absorption capacity and can be used as surfactant and emulsifier therefore provide improved absorption properties and improved medicinal delivery from the adhesive.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

6. Applicant's arguments with respect to claims 1, 6-13, 21, 26, 37-42 over WO '858 in view of CA '251, JP '545 and GB '683 have been considered but are moot in view of the new ground(s) of rejection. Applicants mainly argued CA '251 reference, which is not part of the present rejection.

Applicants argue WO '858 does not support the "one or more amphiphilic block copolymers" limitation of the present claims. In response to this argument, it is argued that amphiphilic block copolymers are taught by WO '858 in combination with JP '545 and GB '683. The present invention as a whole is taught by the combination of the references and the present invention would have been prima facie obvious in the meaning of U.S.C. 103(a).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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